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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. EV 532895255 US

INVENTOR(S)		
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Additional inventors are being named on the one *separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

Artificial Disk for Deformity Correction

Direct all correspondence to: **CORRESPONDENCE ADDRESS**

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ENCLOSED APPLICATION PARTS *(check all that apply)*

[X] Specification *Number of Pages* 8

[X] Drawing(s) *Number of Sheets* 1

[ ] Application Data Sheet. See 37 CFR 1.76

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[X] Applicant claims small entity status. See 37 CFR 1.27.

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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

[X] No.

[ ] Yes, the name of the U.S. Government agency and the Government contract number are:

Respectfully submitted,

SIGNATURE

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Date June 30, 2004

REGISTRATION NO. 35,621
(if appropriate)
Docket Number: 55485-1

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PROVISIONAL APPLICATION COVER SHEET
Additional Page

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Docket Number 55485-1

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Number 1 of 1 extra pages

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ARTIFICIAL DISC FOR DEFORMITY CORRECTION

Background:

Cervical arthroplasty is an emerging field that offers the promise of restoring normal spinal motion following anterior cervical discectomy. Arthroplasty aims to reduce or eliminate adjacent segment disease (ASD) by maintaining normal spinal biomechanics at the operative level. To accomplish this, an artificial cervical prosthesis must mimic natural spinal biomechanics as closely as possible.

Degeneration of the cervical spine is a universal concomitant of human aging. Neck and arm pain caused by nerve root compression in the cervical spine has been estimated to effect 51% of the adult population. Cervical spondylosis and aging are intimately related, with spondylosis increasing in both prevalence and severity with age. Fortunately, the majority of patients will improve without surgery. In approximately 10-15% of the population, cervical spondylosis is associated with persistent root and cord compression, with approximately 5% ultimately requiring surgery.

Each year, thousands of North Americans undergo surgery for cervical spondylosis. The majority of these procedures involve an anterior discectomy with decompression of the spinal cord and/or nerve root. The primary indication for surgery in the management of cervical spondylosis is refractory radiculopathy and/or myelopathy. Following the discectomy, an anterior interbody fusion is commonly performed. Autologous bone harvested from the iliac crest or cadaveric bone is most commonly used to fill the space created by the removal of the disc. The graft for the interbody fusion can be shaped to

correct underlying deformity of the cervical spine. By contouring the graft one can restore cervical lordosis to a straight or kyphotic spine. Unfortunately, fusion following anterior cervical discectomy has been implicated in the acceleration of cervical spondylotic disease in levels adjacent to the fused segment (adjacent segment disease).

Artificial cervical discs have been implanted for the management of degenerative disc disease producing radiculopathy, myelopathy and/or neck pain. More recently, artificial cervical discs have been adopted for the treatment of cervical trauma. The aim of total disc replacement in the cervical spine is to reproduce the biomechanics of the natural disc. Early clinical results with cervical disc replacements from European and South American trials of single and two-level implantation(s) report favorable clinical outcomes and preserved range of motion at the level of surgery. Range of motion, however, while an important feature of an artificial disc, is only a single measure of spinal biomechanics. The effect of the disc on angulation at the operative level and overall spinal alignment needs to be considered. An early problem identified with the Bryan disc is a tendency for the prosthesis to collapse anteriorly. This kyphotic angulation of the prosthesis has been attributed to the passive nature of the disc. This has important implications as it results in a kyphosis at the level(s) of surgery as well as the overall alignment of the cervical spine. Kyphotic deformity of the cervical spine has been implicated in segmental instability, loss of sagittal balance and the development of clinically significant degenerative disease..

Presently, there are at least four artificial cervical discs undergoing clinical trials worldwide. These include unconstrained devices, such as the Bryan Cervical disc and the PCM cervical disc. These unconstrained devices do not have mechanical stops for range of motion. The Prodisc C and the Prestige LP cervical disc systems are semi-constrained with mechanical stops outside the normal range of motion.

A significant majority of patients with cervical disc disease have either pre-operative straightening of the spine or an element of kyphosis as a result of the degenerative process. All of the available artificial cervical disc replacement systems are passive, and hence are not designed to restore lordosis to a spine that is straight or has focal/global kyphosis. An artificial disc inserted into a straight or kyphotic segment is likely to take on the angle and local biomechanics determined by the facets and ligaments. As such, patients with a pre-operative straight spine may develop post-operative kyphosis and patients with a pre-operative kyphosis have a worsening of the deformity post-operatively.

Possible Solutions:

There are a number of different strategies that can be used with cervical disc replacements to address the need for lordotic correction in the cervical spine. With most the available discs, including the Bryan and Prodisc C, the angle of disc insertion can significantly alter the orientation of the prosthesis. This is related to bone removal and end-plate preparation for the prosthesis. By changing the angle of insertion, the disc can be placed in parallel to the disc space. Because of the passive nature of the prostheses,

this strategy minimizes the risk of introducing kyphosis into the cervical spine. This, however, is only effective in avoiding endplates kyphosis in the prosthesis itself. Unfortunately, by changing only the angle of insertion, one cannot correct an underlying straightening or kyphosis of the cervical spine. Simply changing the angle of insertion is not enough to compensate for a device that does not have sufficient anterior support.

A second strategy to correct deformity involves using the endplates for lordotic correction. This has been utilized by the Link-Charite and Prodisc lumbar disc replacements systems. It has been also used in a single case with the Bryan cervical disc system. Lordotic shells are not routinely available for the present cervical disc replacement systems. This strategy involves changing the thickness of the superior, inferior or both endplates to provide lordotic correction. The articulation between the ball and socket or the nucleus and endplates is not altered. Instead, the thickness of the endplate (usually superior) is changed to correct the kyphosis. The advantage of this system is that the complex geometry of how the prosthesis provides motion is not altered. The disadvantage, however, is that this strategy is not forgiving in that if a mistake is made with either an overly lordotic endplate or an endplate that is not lordotic enough, the revision of the endplate can be difficult at time of surgery and may even preclude the disc space from receiving a disc replacement. As most systems have a coating on the endplates that promote bony ingrowth, revision at a later date may be extremely difficult or even impossible. As there are two surfaces to the endplate – an outer surface that contacts the bone and an inner surface that articulates with the nucleus or core, it is conceivable that by changing the location or geometry of the inner surface, one could

alter the center of rotation and thus achieve lordotic correction. This would be most applicable to metal-on-metal prostheses that function as a "ball and socket" articulation. By changing the location of the "socket" or trough, this could alter how the prosthesis impacts alignment at the level of the disc.

An alternate method of achieving lordotic correction is by changing the nucleus or inner core. The biggest advantage of this approach is that the " nucleus" or core can be easily interchanged and revised. Intra-operatively, instruments can be used to gage the need for lordotic correction and the appropriate nucleus can be inserted. By introducing lordotic correction into the nucleus, it provides the surgeon flexibility, easy of insertion and revisability that the other methods do not provide.

We propose a novel artificial cervical disc that provides the normal range of motion of an intervertebral disc along with the ability to correct straightening or kyphosis of the cervical spine. It possesses elasticity and compressibility, and allows for semi-constrained translation and range of motion of the spinal unit. It will possess maximum durability, biocompatibility, and a means of integrating itself into the spine for long-term stability. Its insertion will be safe, simple, and ideally not add significantly to surgical time. In contrast to the existing cervical disc replacement systems, it will allow the surgeon to restore cervical lordosis to the cervical spine while maintaining motion.

A major advantage of this system will be that the nucleus will be easily revisable. For instance, in cases where the Bryan disc needs revision, the entire disc, including the

endplates, must be removed. In cases where the alignment of the cervical spine changes with time, especially in children and young adults, this new cervical disc replacement system will allow revision of the nucleus, if needed.

The implant consists of three pieces. The endplates will be made in differing sizes to accommodate differences in anatomy. These may be fabricated of titanium alloy, chrome-cobalt-molybdenum (CoCrMo), cobalt 28 chromium molyndenum, cobalt chrome, or other materials suitable for spinal prosthetic inserts. The endplates have two distinct surfaces. The flat surface, which contacts the vertebral endplate, is porous and incorporates a suitable biologic coating, such as calsium phosphate or plasmapore, to promote bony ingrowth for long-term stability (Fig. 1). It will also have two parasagittal keels that provide immediate fixation (Fig.1). The other (inner) surface of the endplates is concave (Fig. 2). This surface articulates with the nucleus. In the middle of this concave surface, there is a single, central keel, which provides an anchor for the nucleus and restricts translation (semi-constrained) (Fig. 2, 3).

The nucleus is composed of a low friction elastomer such as polyurethane or polyethylene (particularly ultra-high molecular weight polyethylene). It has a circular geometric design, with varying degrees of lordosis incorporated into it (Fig. 4a-d). The anterior height of the nucleus would vary, depending on the extent of lordotic correction needed. For instance, the nucleus would be available in various lordotic angles 0, 3° and 6° (Fig. 4b, c, d) as well as differing heights (e.g., 6 and 8 mm). The endplates would slide over the nucleus (Fig. 6, 7). The convex surface of the nucleus would have a

midline groove to allow the nucleus to slide into place between the positioned endplates (Fig. 4a, 5). The central keel on the concave surface of the titanium endplate would fit into the groove of the nucleus (Fig. 6, 7). Before deciding on the final nucleus size, a set of instruments would be inserted to gage the need for lordotic correction.

Claim: An artificial spinal disc comprising

a pair of endplates and a nucleus;

the endplates having a vertebral contact surface and an inner surface, wherein the vertebral contact surface includes at least one parasagittal keel to provide fixation and the inner surface has a concave portion and a central keel to constrain and restrict translation of the nucleus; and

the nucleus comprising a modified sphere with a predetermined horizontal axis aligned to a desired lorthotic correction angle and a pair of opposing midline grooves matching the central keels of the endplates.

Description of figures:

1. Endplate: vertebral contact surface with 2 parasagittal keels and a roughened, coated surface to promote bone ingrowth.

2. Endplate: nucleus contact surface with rectangular keel.

3. Inferior Endplate: anterior view

4. a) Nucleus: View from above demonstrating shape and poster and midline grove

   b) Nucleus: Lateral view with no lordotic correction

   c) Nucleus: Lateral view with 3 degrees lordotic correction. Note the height (Yaxis) is higher anteriorly than posteriorly.

   d) Nucleus: Lateral view with 6 degrees lordotic correction. Note the height (Yaxis) is higher anteriorly than posteriorly.

5. Nucleus: Supero-lateral view demonstrating shape and superior grove

6. Endplate and Nucleus: Cross-sectional view (looking at it head on)

7. Endplate and Nucleus: Lateral view (anterior labeled A and posterior labeled B)

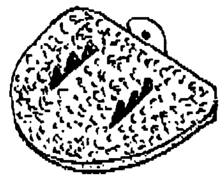


fig 1.

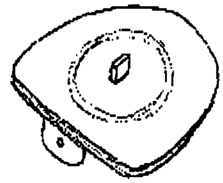


fig 2.

fig 3.

Posterior

Anterior fig 4.a.

0°

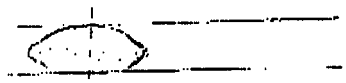
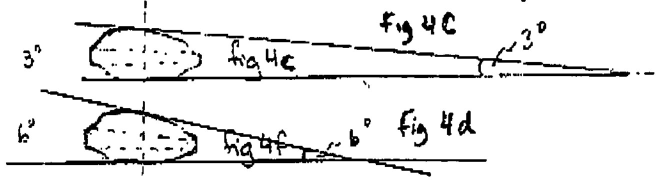


fig 4.b

~~fig 4c~~

~~fig 4d~~



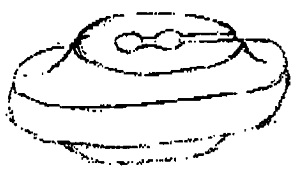


fig 5

fig 6.

Anterior fig 7. Posterior

LRaymond. 15 Mai 2004

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